



PROFESSIONAL IDENTITY & MEDICINES DEVELOPMENT

BY MATTEO NAPOLEONE

The Academy is pleased to continue its series on the perception of Professional Identity in Medicines Development, featuring content from graduates of the Academy Medical Affairs course. We have selected some of the top essays prepared by students of the course. Below is an essay written by Matteo Napoleone. We are grateful, Matteo, for your contributions to the Academy! (See page 2).

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PROFESSIONAL IDENTITY & MEDICINES DEVELOPMENT CONTINUED

"Medicines Development has assumed an increasingly important role in health, the absolute value of mankind, and the Professional Identity is an essential intrinsic requirement. Dealing with public health and patients and for the task we perform in society, a fundamental aspect is to believe strongly in what we do and feel part of something important, knowing that our actions can leave a tangible mark on others and therefore, based on all this, aim to be satisfied with our work: as stated by Rasmussen et al.² the sense of belonging that comes from Professional Identity can lead to job satisfaction and feelings of achievement, while, on the contrary, a weak Professional Identity was found to increase stress and decrease self-confidence and decision-making ability (Anita Fitzgerald).¹

Medicines Development concerns the whole lifecycle of a pharmaceutical/medical device, from R&D to marketing. As we have seen, there are many people involved in this field, but the goal is the same one, working as a single large entity: make a product available to patients who need it and contribute to public health. All of this, however, involves very different professional and personal paths, resulting in a multitude of different Professional Identities. There could be some common aspects (i.e., background, scientific training, etc.) while others could be the result of personal experiences, context and especially socialization (an essential aspect in the Medicines Development field), which define the process of transitions in Professional Identity formation, according to the scheme "identification – reflection – transformation".

As a physician, I think that every patient determines a continuous evolution of the Professional Identity of a physician, and in the same way, as a Medical Affairs professional, I am equally convinced that every experience made in this field (i.e., relationships with patients or HCPs, collaborations with R&D or clinical research, socialization) is the engine of the evolutionary process of Professional Identity in Medicines Development roles."

- Matteo Napoleone

Matteo Napoleone is a Medical Doctor and works as Medical Scientific Relations Advisor in Rare Disease at Pfizer Italy. He joined Pfizer in January 2020 after 4 years' experience in Diagnostic Radiology.

He recently completed IFAPP Academy-King's College London, Medical Affairs in Medicines Development Certification Program. Below is an excerpt from his End of Program essay, in which he was asked to "Characterize Professional Identity in Medicines Development and the need for a Professional Identity for professionals involved in the field."

Thank you, Matteo, for sharing your insights with the Academy and its readers! To read the essay in its entirety, [please click here](#).



EMA: CLINICAL TRIALS & IMPROVED OUTCOMES

On May 20, 2022, a set of Key Performance Indicators (KPIs) to monitor the European clinical trials environment were published to coincide with International Clinical Trials Day, a key date to celebrate the progress achieved in the area of clinical trials and those who make clinical research possible.

The creation and publication of the KPIs is a priority action of the Accelerating Clinical Trials in the EU (ACT EU) program, a joint initiative of the Heads of Medicines Agencies (HMA), the European Commission and EMA to transform the EU clinical trials environment.



The KPIs will be published monthly on the EMA website, pulling information from the two EU clinical trials databases, EudraCT and CTIS. The KPIs measure the number of clinical trial applications submitted under the Clinical Trial Regulation via CTIS and under the Clinical Trials Directive via EudraCT. They also include data on the number of authorized trials that are mono-national and multi-national, commercial and non-commercial, and the number of trials per trial phase and therapeutic area. [Read the full guideline here.](#)

FDA LAUNCHES QUALITY MANAGEMENT INITIATIVE



We often make decisions about our purchases based on basic expectations of quality. When purchasing a laptop, smartphone, a medicine, etc., we take for granted that the manufacturer has factored in certain levels of quality control and quality assurance of the products during production. Planning for malfunctions or supply shortages is not common. However, the pursuit of quality is endless, as the quality standards for products are continually increasing.

As a way to address the increasing quality standards in Medicines Development and to foster a greater commitment to quality in pharmaceutical manufacturing, the FDA sponsored an initiative, “Drug Quality Management Maturity (QMM) Program”.

[Continue reading here.](#)

NEWS FROM THE FDA: ACCELERATED APPROVAL

Is “Accelerated Approval” the way to go? This debate was amplified in part by the agency’s controversial approval in June 2021 of the Alzheimer’s disease drug aducanumab (Aduhelm), whose high price and unclear benefits highlighted key challenges associated with the accelerated-approval process and reignited criticisms of the program.

The program was created in 1992, largely in response to the HIV/AIDS epidemic. This pathway is now used primarily for oncology products. Sponsors sometimes miss deadlines for confirmatory trials, or such trials don’t show evidence of benefit. Despite these problems, there are few constraints on the prices that companies can set for products granted accelerated approval.

[Click here for the complete article.](#)



IS THERE A BENEFIT TO THE COVID-19 PANDEMIC?

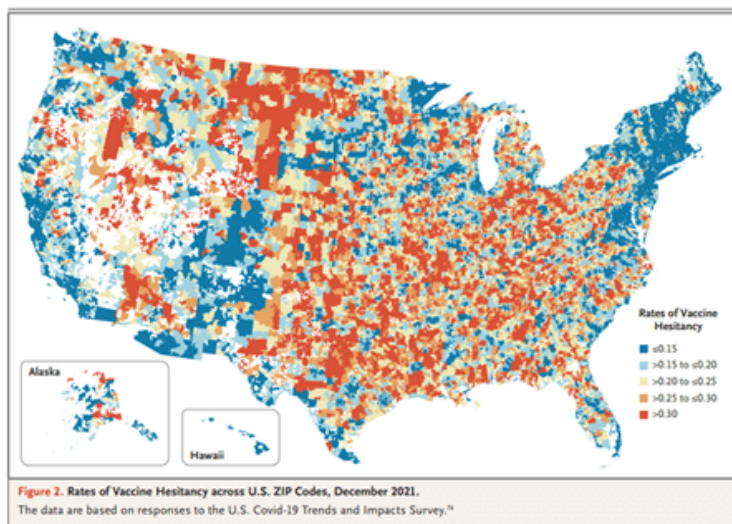
Has the Covid-19 pandemic produced any benefit to mankind? This provocative question is considered at length in an informative publication regarding the development of mRNA vaccines. While the work on mRNA vaccines had gotten a start prior to the pandemic, the urgent need for vaccination to fight the Sars-CoV-2 virus accelerated this work significantly.

“The path to mRNA vaccines took decades, beginning with Katalin Karikó’s seminal work in the 1990s that was aimed at the major pitfall: avoiding the massive inflammation induced by mRNAs injected into mice.”²

[Click here to read the complete article.](#)

VACCINE HESITANCY IN THE UNITED STATES

Two years ago, attitudes towards vaccinations were rarely discussed as it was considered a private matter. However, as Covid-19 made its way into the public eye and quickly evolved into a global pandemic, one's vaccination status became a point of discussion on social media and in the real world. Vaccination campaigns started almost simultaneously in all western countries in January 2021, and people expressed their varying concerns with regard to vaccinations. The media offered a large platform to those more concerned with the potential risks of vaccinations without a great deal of emphasis on the lives saved by vaccines.



The enclosed picture, from the New England Journal of Medicine, is a dramatic visual illustration of the incidence of “vaccine hesitancy” throughout the United States.³

[Click here to read the full publication.](#)

WHY YOU SHOULD ENROLL TODAY IN THE LEADERSHIP COURSE



With enthusiasm, the Academy reminds its readers of the opportunity to complete our Leadership in Medical Affairs course, Module 7. Below the Medical Editor, Domenico Criscuolo, shares a short testimonial of the importance of leadership in general and this course in particular. The course is based on ten lectures and four webinars and includes multiple opportunities for teachers and students to interface in the Discussion Forum.

"In the early 90s, in collaboration with teachers at the SDA Bocconi Business school, I organized the first Italian course on leadership, specifically tailored to Medical Affairs professionals.

It was a unique course in the Italian scene, and it had significant success! The first offering was sold out in just two days, and we quickly organized a second offering, as we decided to limit the number of students to 40.

Over the years, the course gained much interest, and we managed to organize more than 20 editions. In total, approximately 800 Italian professionals attended. I receive great pleasure from encountering former students who proudly remember the course and share several examples with me of when principles learned at the course were utilized in the day-to-day functioning of their jobs. Indeed, all professionals dealing with KOLs, Regulatory Authorities or simply peers on the project team, should know and continuously apply the key elements of leadership. For these reasons, I urge you to enroll in this course and embark on the journey of enhancing and infusing leadership into the daily tasks of your career."

[Ready to lead? Click here to apply.](#)

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